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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	LAKIA TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. Applicant's submission filed on April 20, 2011 is acknowledged. Claim 12 has been amended. Claims 1-6, 8-10, 17 and 18 have been canceled. Please note, claims 17 and 18 have been canceled, however the text of those claims remain present in the claim. Applicant is required to remove the text from said claims in the next response. Claims 12-16 and 19-21 are pending and under examination.

Objection Withdrawn

Claim Objections

2. In view of Applicant's cancellation, the objection to claim 18 because in the second sentence "dues" should be "due" to a hammertoe is withdrawn.

Rejection Withdrawn

3. In view of Applicant's cancellation of claims, the rejection of claims 1-6, 8-10, 17 and 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (This is a new matter rejection) is withdrawn.

4. In view of Applicant's amendments, the rejection of claims 1-5, 8-10 and 12-21 under 35 U.S.C. 102(e) as being anticipated by Sanders (US 2006/0153876 A1; Filed:

2/24/03) in light of American College of Foot and Ankle Surgeons: Hammertoes is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The rejection of claims 12-16 and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Sanders (US 2006/0153876 A1; Filed: 2/24/03), and further in view of Gibbs et al. (BJM, 2002; 325: 1-8) is maintained for the reasons set forth in the previous office action on page 8, paragraph 7.

Applicant argues that:

1) The office must show to those of ordinary skill in the art that the prior art suggest how one should make the claimed composition or device or carry out the claimed process. Sanders fail to recite “warts” entirely and Gibbs discloses nothing related to the SNARE inhibitor described in Sanders.

2) The office must show that the prior art itself would have provided one of ordinary skill in the art with a reasonable expectation of success. The cited references do not provide a reasonable expectation of success; the Gibbs reference illustrates the uncertainty inherent to this field.

3) The prior art must teach or suggest all of the claim limitations. Identifying unrelated prior art references that describe claimed elements cannot support a prima facie case, in absence of a clear rational for combining the references.

4) The office must show a suggestion, teaching or motivation to combine the prior art references.

Applicant's arguments have been considered and are deemed non-persuasive.

Independent claim 12 is drawn to a method for treating skin disorder in a patient in need thereof, the method comprising a step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder, wherein the solution is administered by intradermal injection or subdermal injection with a needle per session; wherein the skin disorder comprises a common wart, a plantar wart or a flat wart and, wherein the botulinum toxin administered is less than the amount used to paralyze a muscle.

With regard to Point 1, the invention is drawn in part, to a method for treating skin disorders in a patient in need thereof, the method comprising a step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder. A suggestion to combine the prior art lies in the fact that botulinum toxin is used in the art to treat pain and the fact that a known symptom of a wart is pain.

Therefore, while Sanders fail to recite “warts”, the combination of references administers a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, reduces at least one symptom of the skin disorder, in this instance said symptom is pain and consequently treats the skin disorder.

With regard to Point 2, contrary to Applicant’s assertion the combination of references has provided one of ordinary skill in the art with a reasonable expectation of success. Sanders discloses methods and formulations that are useful for treatment and/or prevention of disease in mammals such as pain, inflammation, calluses and corns (see paragraphs 0133 and 0136). Gibbs et al. disclose that cutaneous warts can be painful on the soles of the feet and near the nails and suggest that local treatments be used to treat said warts (see page 1, abstract and introduction). Since botulinum toxin is know to treat pain, inflammation, corns and calluses, one would have a reasonable expectation of success that the botulinum toxin would effectively reduce at least one symptom of a skin disorder, in this instance pain, thereby treating the skin disorder.

With regard to Point 3, the prior art teaches and suggest the claimed invention. Sanders discloses methods and formulations that are useful for treatment and/or prevention of disease in mammals such as pain, inflammation, calluses and corns (see paragraphs 0133 and 0136). Gibbs et al. disclose that cutaneous warts can be painful on the soles of the feet and near the nails and suggest that local treatments be used to treat said warts (see page 1, abstract and introduction). The Examiner provided a clear

rationale for combing the references. It was prima facie obvious to modify the invention of Sanders with the teaching of Gibbs et al. to treat, via the reduction of at least one symptom (i.e. pain) of said wart with botulinum toxin because a symptom of warts include pain and inflammation and botulinum toxin is a known agent for treating pain. Moreover, botulinum toxin has unique properties that make them beneficial in medical applications. Said properties are due to the botulinum toxins natural or wild-type form; their ability to block neuromuscular transmission for extended periods; the ability to, in most clinical applications, be used at doses that are below the level of immunological recognition; and lastly because they are remarkably safe for human use when injected into local areas due to the fact that there is little systemic spread of the toxin (see Sanders, paragraph 0009).

With regard to Point 4, in response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, the office has demonstrated a clear rationale, teaching, suggestion and motivation to combine the cited references to arrive at the claimed invention for the reasons set forth supra.

As previously presented, Sanders discloses methods and formulations that are useful for treatment and/or prevention of disease in mammals such as pain, inflammation, hyperpigmentation (seborrheic keratose), calluses and corns (see paragraphs 0133 and 0136). Sanders discloses a method of administering regulated SNARE inhibitors by local administration or administration methods well known in the art such as intramuscular, intradermal, parenteral and subcutaneous injections (see paragraph 0118). Sanders et al. disclose that the regulated SNARE inhibitors are readily commercially available and are, for example, botulinum toxin serotypes A, B, C1, D, E, F, G; available under Botox™ (serotype A) and Myocloc™ (see paragraphs 0067-68). Sanders discloses that for local injection, the compounds of the invention can be formulated in physiologically compatible aqueous solutions, such as Hank's solution, or physiological saline buffer (see paragraph 0125). Moreover, Sanders discloses that the method of the present invention is useful for the treatment, reduction of symptoms and/or prevention of pain or inflammation (see paragraph 0137). Lastly, Sanders discloses that dosages and therapeutically effective amounts of botulinum toxin range from 0.001 units to about 10,000 units (see paragraph 0132).

Sanders does not specifically disclose that the skin disorder comprises a wart, which is a common wart, a plantar wart or a flat wart as recited in claim 6.

Gibbs et al. disclose that cutaneous warts can be painful on the soles of the feet and near the nails and suggest that local treatments be used to treat said warts (see page 1, abstract and introduction).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sanders with the teaching of Gibbs et al. to treat, via the reduction of at least one symptom (i.e. pain) of said wart with botulinum toxin because a symptom of warts include pain and inflammation and botulinum toxin is a known agent for treating pain. Moreover, botulinum toxin has unique properties that make them beneficial in medical applications. Said properties are due to the botulinum toxins natural or wild-type form; their ability to block neuromuscular transmission for extended periods; the ability to, in most clinical applications, be used at doses that are below the level of immunological recognition;

and lastly because they are remarkably safe for human use when injected into local areas due to the fact that there is little systemic spread of the toxin (see Sanders, paragraph 0009).

One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for a method of treating skin disorders in a patient in need thereof.

Since the claimed method steps were known in the prior art and one skilled in the art could have combined the steps as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. See the recent Board decision *Ex parte Smith,--USPQ2d--,* slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
5/2/11

/VANESSA L FORD/
Primary Examiner, Art Unit 1645